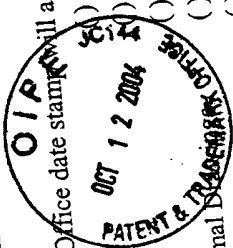


Applicant: Smith, S. Filing Date: 7/30/03  
Serial No: 10/630,562 Art Unit: 3738  
Examiner: Isabella, D. Attorney Docket: 760-12 DIV/CON  
Certificate of Mailing Dated: 10/7/04 Confirmation No.: 8643  
Express Mail Label No.: \_\_\_\_\_

The U. S. Patent and Trademark Office date stamp will acknowledge receipt of the following:

<input type="checkbox"/> Amendment	<input type="checkbox"/> Mo. Extension of Time
<input type="checkbox"/> Assignment	<input type="checkbox"/> IDS w/PTO 1449 & References
<input type="checkbox"/> Patent Application	<input type="checkbox"/> Small Entity Statement
<input type="checkbox"/> _____ Sheets of (In)Formal Declaration	<input type="checkbox"/> Issue Fee
<input type="checkbox"/> Declaration/Power of Attorney	<input type="checkbox"/> Check(s) _____
<input type="checkbox"/> Response to Notice of Missing Parts	<input checked="" type="checkbox"/> Itemized Postcard
<input type="checkbox"/> _____ Yr. Patent Maintenance Fee	<input checked="" type="checkbox"/> Response (5 pgs)
<input type="checkbox"/> Trademark Application	<input checked="" type="checkbox"/> Declaration (23 pgs)
<input type="checkbox"/> Drawing ( ) Specimen (x3) ( ) Letter	
<input type="checkbox"/> Transmittal with Fee Authority (x2)	
<input type="checkbox"/> _____	

JSS/bjt (0876)  
HOFFMANN & BARON, LLP



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Smith, S.

Examiner: Isabella, D.

Application No.: 10/630,562

Group Art Unit: 3738

Filed: July 30, 2003

Docket: 760-12 DIV/CON

For: HELICALLY FORMED  
STENT/GRAFT ASSEMBLY

Dated: October 7, 2004

Confirmation No.: 8643

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to: Commissioner for Patents, Alexandria, VA 22313

Dated: October 7, 2004

Signature: Barbara Thomas

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE PURSUANT TO 37 C.F.R. §1.111**

Sir:

In response to the Office Action dated July 8, 2004, a reply to which is due October 8, 2004, please consider the following:

Remarks/Arguments begin on page 2 of this submission.

Application No.: 10/630,562  
Amendment and Response dated October 7, 2004  
Reply to Office Action of July 8, 2004  
Docket No.: 760-12 DIV/CON  
Page 2

**Remarks/Arguments:**

**Introduction**

Claims 1-13 are pending.

**Section 102 Rejections**

Claims 1, 2, 4, 5, 8, 9 and 11-13 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,063,111 to Hieshima et al (hereinafter "Hieshima"). As noted by the Examiner, the Hieshima reference is applied under the provisions of 35 U.S.C. §102(e), having an issue date subsequent to the filing date of the priority application of the present application, but having a filing date prior thereto.

Submitted herewith is a declaration of the inventor, Scott Smith, pursuant to 37 C.F.R. §1.131. In that declaration, the inventor attests to conception of the invention at a date prior to the filing date of the Hieshima reference and also sets forth evidence which establishes due diligence from a date just prior to the filing of the Hieshima Patent to the filing date of the present application.

Accordingly, it is respectfully submitted that the Hieshima reference should be removed as a cited reference against the claims of the present invention.

Claims 1, 2, 4, 5, 8, 9 and 11-13 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,042,605 to Martin et al. (hereinafter "Martin"). Applicant respectfully traverses.

The invention as presently defined by independent claim 1 is directed to a stent/graft composite device formed from a flat preformed planar strip and stent assembly comprising an

elongate preformed non-textile planar strip of polymeric graft material having first and second opposed surfaces and a planar stent attached onto one of said opposed flat surfaces of said strip to form said flat strip assembly, said strip assembly being helically wound into a continuous tubular structure.

In direct contrast, Martin discloses that a stent wire is to be helically wound around a mandrel to form a tubular stent. (Martin, column 13, lines 12-14). Graft material is also placed over a mandrel to form an inner tubular liner. (Martin, column 14, lines 9-11). The tubular stent is then positioned over the inner liner to form a stent-graft. (Martin, column 14, lines 13-15). A flat ribbon PTFE is then wrapped around the exterior surface of the stent. (Martin, column 14, lines 18-22).

Thus, Martin discloses a prosthesis which is formed by individually placing different components of the prosthesis over a mandrel. Accordingly, Martin fails to disclose a stent/graft composite device formed from a flat preformed planar strip and stent assembly. Therefore, because Martin fails to disclose each and every element as set forth in independent claim 1, withdrawal and reconsideration of the rejection of claim 1 and all claims dependent therefrom are respectfully requested.

Further, Martin fails to teach or suggest a stent/graft composite device formed from a flat preformed planar strip and stent assembly as Martin teaches that its prosthesis is to be formed by individually placing different components of the prosthesis over a mandrel. Thus, claim 1 and all claims dependent therefrom are patentably distinct over Martin

Claims 1-9, and 11-13 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,264,684 to Banas et al. (hereinafter "Banas"). Applicant respectfully traverses.

Banas discloses a polymeric cladding 11 and a support wire member 14 which may be helically wound to an abluminal wall surface 17 of a tubular substrate 12. (Banas, column 7, line 38, to column 8, line 6). The wire member 14 is encapsulated within the cladding 11 (see Figures 5-11) by coextrusion or dipping techniques. (Banas, column 7, lines 56-67). Alternatively, as shown in Figure 12, wire member 14 may be placed in a longitudinally extending recess dimensioned into the cladding 11 for receiving and retaining the wire member 14. (Banas, column 7, lines 57-63).

Thus, Banas discloses either a wire encapsulated in a cladding assembly or a complex three-dimensionally formed cladding for receiving its wire member.

In contrast, the present invention is formed from an essentially flat planar strip having a planar stent attached onto one of the opposed essentially flat planar surfaces of the strip. Being flat, the planar strip does not have significant three-dimensional features, such as the recess or groove of Banas. (See specification, paragraph [0058]). Also, because the wire of the present invention is attached onto one of the flat surfaces of the planar strip to form a planar strip assembly, such a strip assembly is not an encapsulated assembly formed by coextrusion or dipping techniques, as disclosed by Banas.

Therefore, Banas fails to disclose each of the claimed features of the present invention. Thus, reconsideration and withdrawal of the rejections under 35 U.S.C. §102(e) of independent claim 1 and all claims dependent therefrom are respectfully requested.

Furthermore, Banas fails to teach or suggest the present invention as set forth in independent claim 1. Banas fails to teach or suggest a flat planar strip which is substantially free of a groove or recess and a planar stent attached to one of the strip's planar surfaces. Banas teaches that planar wires must be encapsulated in graft material or must be placed in a

Application No.: 10/630,562  
Amendment and Response dated October 7, 2004  
Reply to Office Action of July 8, 2004  
Docket No.: 760-12 DIV/CON  
Page 5

groove or recess of graft material for forming its stent/graft. Therefore, the present invention is patentably distinct over Banas.

**Summary**

Therefore, Applicant respectfully submits that independent claim 1, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461.

Respectfully submitted,

---

John S. Sopko  
Registration No.: 41,321  
Attorney for Applicant(s)

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike  
Syosset, New York 11791  
(973) 331-1700

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Smith, S.

Examiner: Isabella, D.

Serial No.: 10/630,562

Group Art Unit: 3738

Filed: July 30, 2003

Docket: 760-12 DIV/CON

For: HELICALLY FORMED  
STENT/GRAFT ASSEMBLY

Dated: October 7, 2004

Confirmation No.: 8643

I hereby certify this correspondence is being deposited with the  
United States Postal Service as first class mail, postpaid in an envelope,  
addressed to: Commissioner for Patents, Alexandria, VA 22313.

Dated: October 7, 2004

Signature: Barbara Thomas 

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION OF PRIOR INVENTION IN THE UNITED STATES  
TO OVERCOME A CITED PATENT UNDER 37 C.F.R. §1.131**

Sir:

1. I, Scott Smith, a citizen of the United States, residing at 6950 Country Road #10, Chaska, Minnesota 55318, is the inventor of the above-identified application.

2. At the time of the invention thereof and continuously to the present, I was and am an employee of SCIMED Life Systems, Inc., assignee of the present application. I submit this declaration to establish completion of the invention set forth in this application in the United States at a date prior to March 31, 1998, i.e., the effective date of U.S. Patent No. 6,063,111 to Hieshima et al. which was cited by the Examiner in an Office Action mailed, July 8, 2004.

3. From the documents submitted herewith and as set forth hereinbelow, it can be seen that the invention set forth in the claims of this application was completed in the United States before March 31, 1998, which is a date earlier than the U.S. filing date of the '111 Patent. Such completion being evidenced by conception of the invention prior to the effective date of the reference coupled with due diligence from prior to that date to the subsequent filing of the application. Exhibits A through I are submitted in support thereof. The Exhibits A through I are being submitted with their dates redacted. The actual document dates of Exhibits A and B are prior to March 31, 1998. The actual document dates of Exhibits C through I are after March 31, 1998, but prior to constructive reduction to practice date of July 2, 1999, i.e., the filing date of the parent Application No. 09/345,026, now U.S. Patent No. 6,364,904. A brief description of the documents being submitted are as follows:

- a. An invention disclosure (Exhibit A) bearing a date signed by myself, the inventor, prior to March 31, 1998, the filing date of the '111 Patent. The invention disclosure describes the invention as substantially set forth in the claims of the above-referenced application. The invention disclosure describes the use of a flat stent strip for use as a covered stent. The stent or stent strip is described being compressed against a layer or layers of flat ePTFE to form an assembly. This assembly is described as then being wrapped on a mandrel followed by laminating the components together. Alternately, the assembly may be laminated together prior to being wrapped on a mandrel.
- b. A letter prior to March 31, 1998 (Exhibit B) from Assignee's Patent Attorney to outside patent counsel enclosing the invention disclosure of Exhibit A and



requesting the preparation of a patent application.

- c. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit C) from outside patent counsel to Assignee's Patent Attorney reporting three application matters, including one for the parent (Docket No. 760-12, now U.S. Patent No. 6,364,904) of the above-referenced application, for the above-mentioned and related invention disclosures.
- d. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit D) from outside patent counsel to myself, the inventor, reporting the enclosure of drafts of three applications, including a draft of the parent of the above-referenced application.
- e. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit E) from Assignee's Patent Attorney to outside patent counsel reporting comments on the draft parent application.
- f. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit F) from outside patent counsel to Assignee's Patent Attorney reporting the preparation of three application drafts, including a draft of the above-mentioned parent patent application, for further review by myself, the inventor.
- g. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit G) from the Assistant to Assignee's Patent Attorney to outside patent counsel reporting additional comments relating to three draft

applications, including the above-mentioned parent application.

- h. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit H) from outside patent counsel to Assignee's Patent Attorney reporting the enclosure of three additional application drafts, including a draft of the above-mentioned parent application for review.
- i. A letter dated after March 31, 1998 and prior to constructive reduction to practice date of July 2, 1999 (Exhibit I) from Assignee's Patent Attorney to outside patent counsel enclosing three executed patent applications, including the above-mentioned parent application, and requesting that the application be filed.

4. This declaration is being submitted in response to a Non-Final Office Action issued by the Examiner and therefore is believed to be timely filed.

5. The above-referenced exhibits establish a date of invention prior to March 31, 1998, the filing date of the '111 patent, and further establish diligence from that date to the filing date of the parent application, namely July 2, 1999.

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

*SPS*  
Dated: *Sept 28, 2004*

  
Scott Smith

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike  
Syosset, New York 11791  
(973) 331-1700

SCIMED

Invention Disclosure Form

page 1 of \_\_\_\_

Descriptive Title of Invention: Spiral Wound Spiral StentInventor (s): Scott Smith Brian Brown

Date of Invention: \_\_\_\_\_

Date of First Drawing: \_\_\_\_\_

Date of First Written Description: \_\_\_\_\_

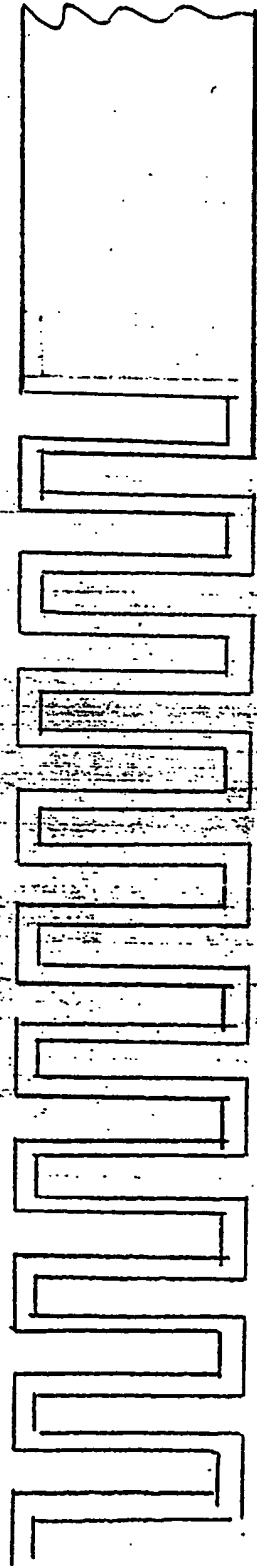
Date of Disclosure: \_\_\_\_\_

Internal: \_\_\_\_\_ To Whom: \_\_\_\_\_ (circle one)  
Written OralExternal: \_\_\_\_\_ To Whom: \_\_\_\_\_ (circle one)  
Written OralDescription of Invention: Wound Spiral Slotted StentField of Application: StentsRelated SCIMED devices or concepts: Brown Brown Stent Designs  
ArchieDescription: Stent Formed From a Nitinol or other metal  
ribbon which is cut, wound, attached or welded, and, if  
self expanding, bent set in expanded shape.Unique feature of invention: used readily available M.T. ribbon (rolled wire)  
with minimal welding or bonding to produce a self-expanding stent  
produced economically using flat slat techniques like etching, wire EDM or laser  
cutting.Advantages of unique feature: these processes can be performed  
faster and with higher quality than with tubular shapes.  
Further more, walls can be positioned to maximize impact  
on expansion properties.



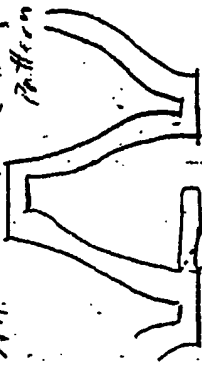
wrapped spiral zig-zag offset sheet.

cut  
↓



cut  
↑

Alternate "open" cutting  
Pattern



For Connector  
 Bend & Heat  
 set into "cut"  
 Position

connector (weld or polymer)



000927

000941

7:00 PM  
EST

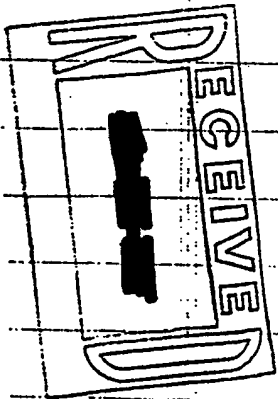
duplicate and extension of Design  
for endo vascular Start and Start  
graft design.

1. Spiral Slotted tube Start (Note - See Bruns Bruns notebook)
2. Spiral etch, fold, weld Start (EFW) ↳ Earlier versions.
3. Spiral flat Strip Start
4. Connections or articulation for above Start
5. Covered Starts made from start #3 above
  - a. 2 or More Layer Sandwich
  - b. Spiral wrap w/ encapsulated Start
6. Multi-helix version of Above Starts 1, 2, 3, 4, 5

1. a cut or etched slotted tube start  
with the slots distributed in a helical

horizontal

end view

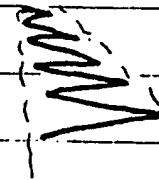


Radius  -

Spiral 




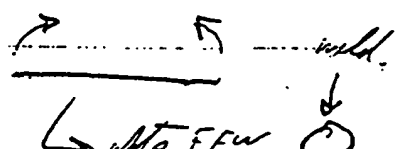
Possible end treatment



2. Start #1 formed from a flat sheet and  
rolled into a cylinder and welded or  
otherwise attached.

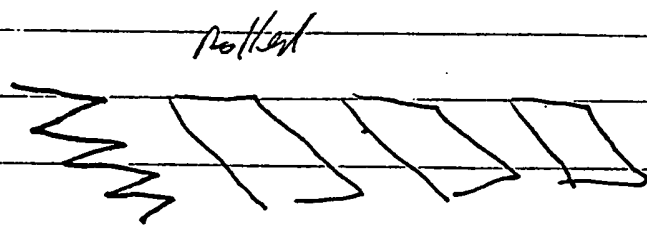
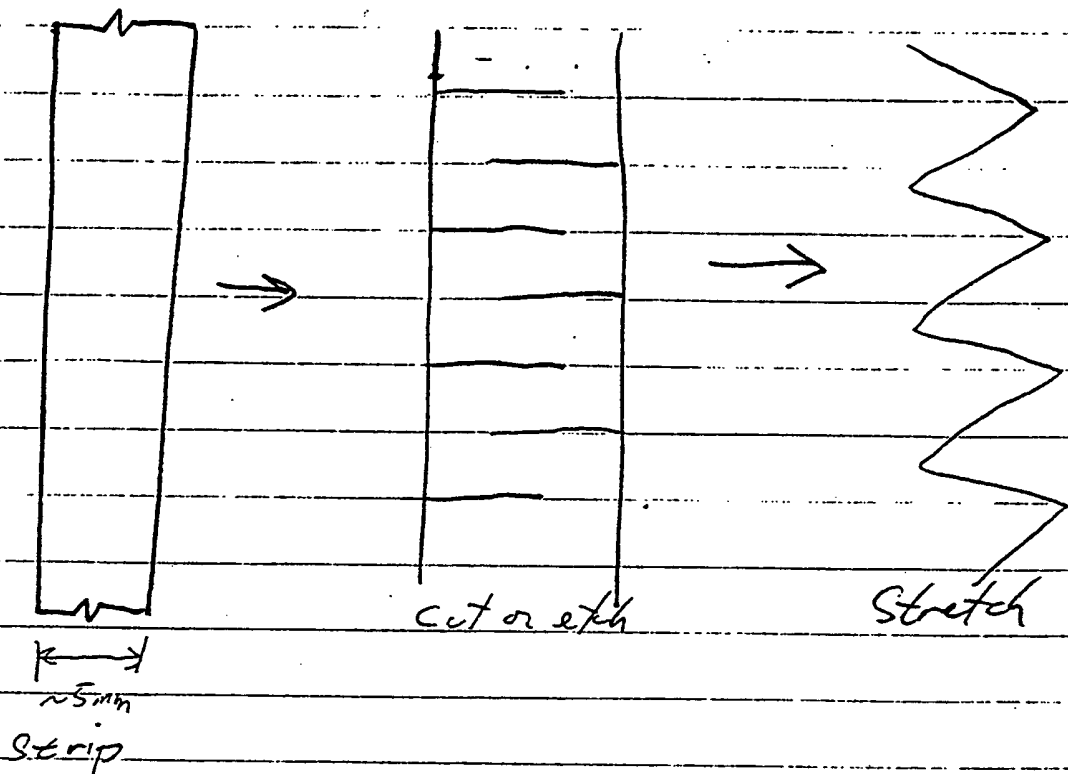
end view

Invented by 

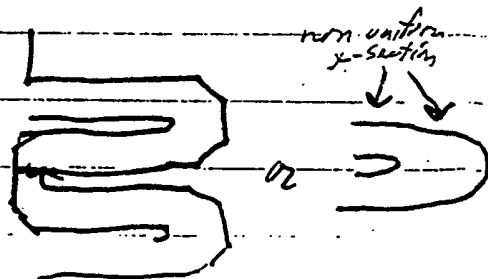


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3. Since large, thin, Flat sheet not readily available,  
use Long thin Strip to produce N.T. Sheet.



Possible specific design example:



Invented by: *Bob Smith*

Witnessed by: *Charles E. [redacted]*

4. Connection or Articulation: Specific Pattern of Connection between Stent Segments results in improved (More Uniform, Lower Force, Less Kinking) flexibility of Stents eg. Radius 18 Stents  
3 Connectors  
each Segment offset by 3 Stents

Intern: 30 Stents  
3 Connectors  
each Segment offset by 5 Stents

Spiral Stents allow for Uniform Connector distribution using other #'s of Stents. Additionally, the Connector and Stents are distributed more uniformly Axially as well.

5. Covered Stents can be made from or Follow:

1. <sup>wrap</sup> ~~wrap~~ a PTFE Membrane on Mandrel
2. wrap Stent or Load Stent on Mandrel over a PTFE
3. Apply more a PTFE over top.
4. heat & Compress to Bond Layers Together

Alternatively,

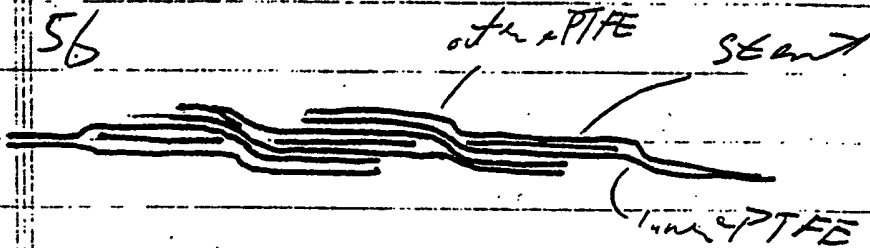
1. Compress strip Stent (#3) between 2 layers of Flat a PTFE and heat, then wrap on Mandrel and re heat. Actually, 1<sup>st</sup> heat step not necessary.

Invented by: ~~Robert Smith~~ ~~Philip Smith~~



000941

56



6, seams can be multiple helix's to obtain still other connect distribution, use separate materials, or obtain different mechanical characteristics.

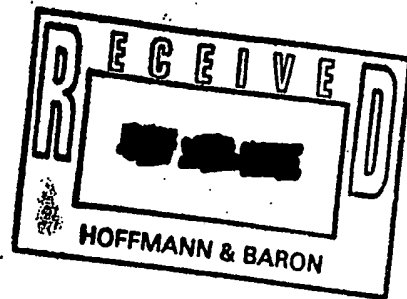
Invented by: *[Signature]* *[Redacted]*  
*[Signature]* *[Redacted]*

witness: *[Signature]*  
*[Redacted]*

**SCIMED®**  
Boston Scientific Corporation

SCIMED Life Systems, Inc.  
One SCIMED Place  
Maple Grove, MN 55311-1566  
612-494-1700

EXHIBIT B



[REDACTED]

Daniel A. Scola, Jr., Esq.  
HOFFMAN & BARON  
1055 Parsippany Boulevard  
Parsippany, NJ 07054

RE: Invention Disclosures 922, 927 and 941  
SCIMED File Nos.: SM-P0357-US01 and SM-P0406-US01

Dear Dan:

Under letters of [REDACTED] and [REDACTED] of this year, you received copies of the three above-mentioned disclosure forms. To insure that you have complete sets, another copy of each is enclosed. At this time, I would like you to begin preparing the two patent applications directed to these inventions. Invention Disclosure 927 and parts of Invention Disclosure 941 should be included in a patent application directed to Spiral Wound Stents (our file SM-P0357-US01). I have enclosed a copy of SCIMED's Application WO95/31945. Invention Disclosure 922 and the remainder of 941 are directed to an improved vascular stent graft device (our file SM-P0406-US01).

If you have any questions concerning these disclosures, feel free to contact me.

Sincerely,

Luke Dohmen  
Sr. Patent Attorney

LD:dl  
Enclosure

## HOFFMANN &amp; BARON, LLP

ATTORNEYS AT LAW  
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 KEVIN C. HOOPER†  
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 ROBERT F. CHISHOLM\*\*  
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 FAX (516) 822-3552

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 \*\* ALSO ADMITTED IN NY  
 \*\*\* ADMITTED IN NY & CONN ONLY  
 □ ALSO ADMITTED IN CONNECTICUT  
 + ADMITTED IN WASHINGTON, D.C. ONLY  
 † ALSO ADMITTED IN PENNSYLVANIA  
 ‡ ADMITTED IN PENNSYLVANIA ONLY  
 ∞ ADMITTED IN VIRGINIA ONLY

**VIA FACSIMILE**

Luke Dohmen, Esq.  
 SCIMED Life Systems, Inc.  
 One SCIMED Place  
 Maple Grove, MN 55311-1566

Re: SCIMED Patent Applications  
Our Dockets: 760-6; 760-7; 760-12

Dear Luke:

In response to your request of today, listed below is the information on the three (3) above-identified SCIMED patent applications:

Our Docket: 760-6  
 SCIMED Reference: ID 927 and Part of ID 941  
 File # SM-P0357-US01  
 Title: Spiral Wound Stent  
 Inventors: Scott Smith and Brian Brown

Our Docket: 760-7  
 SCIMED Reference: ID 922  
 File # SM-P0406-US01  
 Title: Improved Composite Vascular Graft  
 Inventor: Scott Smith

Our Docket: 760-12  
 SCIMED Reference: ID 941  
 File # SM-P0406-US01  
 Title: Improved Stent/Graft Device  
 Inventor: Scott Smith

Luke Dohmen, Esq.

Page 2

If you need anything further, please do not hesitate to contact us.

Sincerely,



Daniel A. Scola, Jr.

DAS/kg

DAVID D.  
**HOFFMANN & BARON, LLP**

ATTORNEYS AT LAW

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\* NOT ADMITTED IN N.J.  
+ SENIOR ATTORNEYS

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R. GLENN SCHROEDER\* MARK E. BARON  
GLENN T. HENNEBERGER\* WAYNE L. ELLENBOGEN  
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ANTHONY E. BENNETT\* SAMIR R. PATEL\*  
KEVIN C. HOOPER\* WILLIAM D. SCHMIDT\*  
ROBERT F. CHISHOLM\* MICHAEL P. MUNRO\*  
GREGORY W. BACHMANN\* PATRICK J. HOFFNER\*

  
**VIA FACSIMILE**

Scott Smith  
SCIMED Life Systems, Inc.  
One SCIMED Place  
Maple Grove, MN 55311-1566

Re: New Patent Applications  
Our Docket: 760-6; 760-7 and 760-12

Dear Scott:

Please find enclosed the application drafts for the above-referenced applications, which respectively correspond to the following inventions:

Our Docket:	760-6
SCIMED Reference:	ID 927 and Part of ID 941
Title:	File # SM-P0357-US01
Inventors:	Spiral Wound Stent
	Scott Smith and Brian Brown
Our Docket:	760-7
SCIMED Reference:	ID 922
Title:	File # SM-P0456-US01
Inventor:	Improved Composite Vascular Graft
	Scott Smith
Our Docket:	760-12
SCIMED Reference:	ID 941
	File # SM-P0476-US01

Mr. Scott Smith  
[REDACTED]

Page 2

Title: Helically Formed Stent and Graft Assembly  
Inventor: Scott Smith

With respect to the IMPROVED STENT/GRAFT DEVICE (760-12) it is a partial draft with claims, figures, and background of invention included.

Please forward a copy of the SPIRAL WOUND STENT (760-6) application draft to Brian Brown. Dan Scola of this office will discuss the applications with you tomorrow.

In the meantime, should you any questions or comments, please communicate them with us at your convenience.

Very truly yours,



Mark E. Baron

MEB/mjm  
Enclosures

cc: L. Dohmen

[REDACTED]

Daniel J. Scola, Esq.  
Hoffmann & Baron, LLP  
1055 Parsippany Blvd.  
Parsippany, NJ 07054

**PRIVILEGED & CONFIDENTIAL**

Re: U.S. Draft Patent Application for:  
***HELICALLY FORMED STENT AND GRAFT ASSEMBLY***  
Your File: 760-12  
Our File: SM-P0406-US01

Dear Dan:

Enclosed are our comments for the above-referenced draft patent application. Please contact me after you have had a chance to review the enclosed material.

Thank you for your assistance in this matter.

Very truly yours,

*Luke Dohmen /ed/*  
Luke Dohmen

Enclosure

LD/ld

# HOFFMANN & BARON, LLP

ATTORNEYS AT LAW

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PATRICK J. HOFFNER\*  
JAMES F. HARRINGTON  
KEVIN E. McDERMOTT\*  
DAVID P. PETROFF\*  
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NANCY A. BIRD\*  
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6900 JERICHO TURNPIKE  
SYOSSET, N.Y. 11791  
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FAX (516) 822-3552

\* NOT ADMITTED IN N.J.  
+ SENIOR ATTORNEY

Luke Dohmen, Esq.  
SCIMED Life Systems, Inc.  
One SCIMED Place  
Maple Grove, MN 55311-1566

Re: New Patent Application For:  
SPIRAL WOUND STENT  
Our Docket: 760-6

New Patent Application For:  
IMPROVED COMPOSITE VASCULAR GRAFT  
Our Docket: 760-7

New Patent Application For:  
HELICALLY FORMED STENT/GRAFT ASSEMBLY  
Our Docket: 760-12

Dear Luke:

We have prepared the above-identified applications in final form for filing in the U.S. Patent and Trademark Office. We enclose copies of each application including formal papers for execution.

We ask that you arrange to have the inventors review the applications and execute the formal papers where indicated. Once the papers have been executed, please return the papers to us and we will promptly file the applications in the U.S. Patent and Trademark Office.

If during the review process, the inventors have any changes they wish to make to the applications, please have them make the changes in ink and initial and date the changes in the margin. In that manner, we can still file the application as executed.



Luke Dohmen, Esq.  
[REDACTED]

Page 2

If you have any questions or comments or wish to discuss the applications or the formal papers in further detail, please do not hesitate to contact us.

Very truly yours,



Salvatore J. Abbruzzese

SJA/mjm  
Enclosures

**Boston  
Scientific  
SCIMED**

Scimed Life Systems, Inc.  
One Scimed Place  
Maple Grove, MN 55311-1566  
612.494.1700  
www.bsci.com

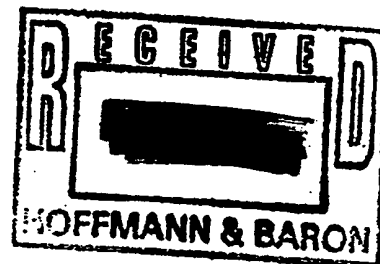
Salvatore J. Abbruzzese, Esq.  
Hoffmann & Baron, LLP  
1055 Parsippany Blvd.  
Parsippany, NJ 07054

**PRIVILEGED & CONFIDENTIAL**  
via Federal Express

Re: U.S. Patent Applications for:

- ***SPIRAL WOUND STENT***
- ***IMPROVED COMPOSITE VASCULAR GRAFT***
- ***HELICALLY FORMED STENT/GRAFT ASSEMBLY***

Your Files: 760-6; 760-7; and 760-12  
Our Files: SM-P0357-US01; SM-P0456-US01; and SM-P0406-US01



Dear Mr. Abbruzzese:

Per Luke Dohmen's request, enclosed please find comments for each of the above-referenced patent applications. At your earliest convenience, would you please prepare a final draft for each application and forward these to Scimed for final review.

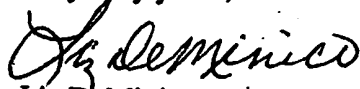
In addition, would you please add Chris Brodeur as a co-inventor to the "*Improved Composite Vascular Graft*" application. His complete name and address are as follows:

Christopher Brian Brodeur  
741 98<sup>th</sup> Lane NE  
Blaine, MN 55434  
Citizenship: U.S.A.

I have retained the formal papers for the other two applications and will have them executed upon receipt of the final draft patent applications.

In the meantime, if I can be of further assistance, please contact me at (612) 494-2532. Thank you for your prompt attention and assistance in this matter.

Very truly yours,

  
Liz DeMinico  
Assistant to Luke Dohmen

Enclosures

cc: L. Dohmen (less enclosures)

HOFFMANN & BARON, LLP

ATTORNEYS AT LAW

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PARSIPPANY, NEW JERSEY 07054

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+ SENIOR ATTORNEY

Luke Dohmen, Esq.  
SCIMED Life Systems, Inc.  
One SCIMED Place  
Maple Grove, MN 55311-1566

Re: New Patent Application For:  
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New Patent Application For:  
IMPROVED COMPOSITE VASCULAR GRAFT  
Our Docket: 760-7

New Patent Application For:  
HELICALLY FORMED STENT/GRAFT ASSEMBLY  
Our Docket: 760-12

Dear Luke:

Further to our previous correspondence, we have prepared the above-identified applications in final form for filing in the U.S. Patent and Trademark Office. The final form of these applications have been prepared incorporating the comments provided to us by the inventors. Included with each copy of the application are formal papers including a Combined Declaration and Power of Attorney as well as an Assignment of Invention form.

We ask that if you and the inventors find these applications to be acceptable, please execute the formal papers and return them to us. Upon receipt of the formal documents, we will arrange to file the applications in the U.S. Patent and Trademark Office.

Luke Dohmen, Esq.

Page 2

If you or the inventors have any questions or comments or wish to discuss any portions of the application in further detail, please do not hesitate to contact us.

Very truly yours,

A handwritten signature in black ink, appearing to be 'SJA', enclosed within a hand-drawn oval.

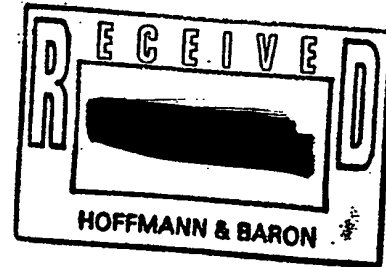
Salvatore J. Abbruzzese

SJA/mjm  
Enclosures

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One Scimed Place  
Maple Grove, MN 55311-1566  
612.494.1700  
www.bscl.com

**VIA FEDERAL EXPRESS**

Salvatore J. Abbruzzese  
HOFFMAN & BARON  
1055 Parsippany Boulevard  
Parsippany, NJ 07054



RE: SPIRAL WOUND STENT  
Our File No.: SM-P0357-US01  
Your File No.: 760-6

IMPROVED COMPOSITE VASCULAR GRAFT  
Our File No.: SM-P0456-US01  
Your File No.: 760-7

HELICALLY FORMED STENT/GRAFT ASSEMBLY  
Our File No.: SM-P0406-US01  
Your File No.: 760-12

Dear Sal:

Enclosed are the executed patent applications with regard to the above-identified matters.  
Please place these applications on file with the United States Patent and Trademark  
Office as soon as possible.

If you have any questions, please call me.

Sincerely,

Luke Dohmen  
Sr. Patent Attorney

LD:dl  
Enclosures



# UNITED STATES PATENT AND TRADEMARK OFFICE

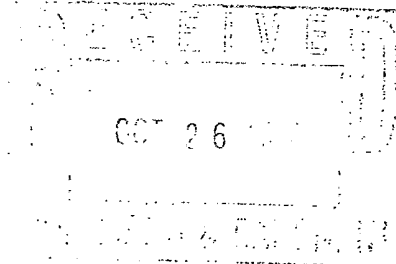
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,562	07/30/2003	Scott Smith	760-12 DIV/CON	8643
23869	7590	10/22/2004	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	

OCT 25 2004

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.





UNITED STATES PATENT AND TRADEMARK OFFICE

SWID/630562  
COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
P.O. Box 1450  
ALEXANDRIA, VA 22313-1450  
www.uspto.gov

Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment document filed on 10/12/04 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required. **Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted.** 37 CFR 1.121(h).

THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☒ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☒ C. Other Amendment is unsigned.
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other \_\_\_\_\_
- ☐ 3. Amendments to the drawings: \_\_\_\_\_
- ☐ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following 7 status identifiers: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New) and (Not entered).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☐ E. Other: \_\_\_\_\_

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP Sec. 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf>.

If the non-compliant amendment is a **PRELIMINARY AMENDMENT**, applicant is given ONE MONTH from the mail date of this letter to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and this ONE MONTH time limit is not extendable. JH/d  
11/02

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION** (including a submission for an RCE), and since the amendment appears to be a *bona fide* attempt to be a reply (37 CFR 1.135(c)), applicant is given a TIME PERIOD of ONE MONTH from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

If the amendment is a reply to a **FINAL REJECTION**, this form may be an attachment to an Advisory Action. The period for response to a final rejection continues to run from the date set in the final rejection, and is not affected by the non-compliant status of the amendment.

[Signature]  
Legal Instruments Examiner (LIE)

703-308-0991  
Telephone No.

Applicant: Smith, S.

Application No: 10/630,562

Filing Date: July 30, 2003

Examiner: Art Unit:

Certificate of Mailing Dated: October 28, 2004

Express Mail Label Number:

Attorney Docket: 760-12DIV/CON

Confirmation No:

The U. S. Patent and Trademark Office date stamp will acknowledge receipt of the following:

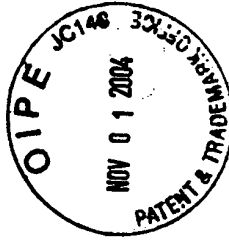
(X) Response to Notice of Non-Complaint Amendment (1pg)

(X) Copy of Notice of Non-Complaint Amendment (2 pgs)

(X) Copy of Response (signed) and Declaration filed on October 7, 2004

(X) Postcard

JSS/bjt (0876)





**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Smith, S.

Examiner: Isabella, D.

Application No.: 10/630,562

Group Art Unit: 3738

Filed: July 30, 2003

Docket: 760-12 DIV/CON

For: HELICALLY FORMED  
STENT/GRAFT ASSEMBLY

Dated: October 28, 2004

Confirmation No.: 8643

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to: Commissioner for Patents, Alexandria, VA 22313

Dated: October 28, 2004

Signature: Barbara Thomas

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO NOTICE OF NON-COMPLIANT AMENDMENT**

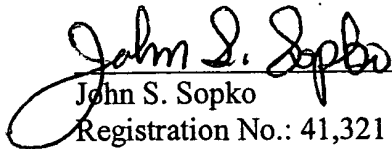
Sir:

This is in response to a Notice of Non-Compliance Amendment dated October 22, 2004, a copy of which is enclosed. A reply is due within one month, i.e., November 22, 2004.

The Response mailed October 7, 2004 and received by the Patent Office on October 12, 2004 was non-compliant as lacking a signature. Enclosed herewith is page 5 of the October 7, 2004 response having the signature of the attorney.

For the convenience of the Office, a duplicate copy of the entire Response is also being submitted herewith.

Respectfully submitted,

  
John S. Sopko  
Registration No.: 41,321  
Attorney for Applicant(s)

HOFFMANN & BARON, LLP  
6900 Jericho Turnpike  
Syosset, New York 11791  
(973) 331-1700